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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,950	12/08/2000	Colin Watts	ERP01.004A	2538

20995 7590 04/21/2006

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,950	WATTS, COLIN	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 7, 2005 AND January 13, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,12-16,18-20,38-42,52-54 and 56-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4,38-41,57-59 and 68* is/are allowed.

6)☒ Claim(s) *12-16,18-20,42,52-54,56,60-67,69 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12072005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a rule 371 continuation of PCT Serial Number PCT/GB99/00963.

Claims 5-11, 17, 21-37, 43-51 and 55 have been canceled.

New claims 69 and 70 have been added.

Claims 1-4, 12-16, 18-20, 38-42, 52-54 and 56-70 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendments filed December 7, 2005 and January 13, 2006 no outstanding ground of rejection is maintained.

The following represent NEW GROUNDS of rejection and necessitate that this Office Action be made NON-FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 12, 15, 16, 18-20, 42, 52-54, 56, 60-67 and 69-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting an immune response in a patient comprising administering one of the N- and C-terminal blocked peptides AENK or KNNE as set forth in or with a peptide of the structure B1-$(X)_n$-Asn-Q wherein Q is a vinylmethylsulfone, chloromethylketone or fluoromethylketone, does not reasonably provide enablement for the full scope of asparaginyl endopeptidase inhibitors comprising any other "group capable of reacting with active site cysteine of asparaginyl endopeptidase." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to inhibitors of asparaginyl endopeptidase comprising an asparagine residue attached to any group "capable of reacting with active site cysteine of asparaginyl endopeptidase." In some claims the letter "Q" defines the "group." However, the specification does not adequately define what constitutes Q or the group. Q is only defined as a group "capable of reacting with the active site cysteine or other active site residue of AEP" in paragraph **[0043]** for example. In addition, the metes and bounds of the phrase "reacting with" have not been established in the specification. For example, does the term mean binding covalently, non-covalently or result in cleavage of the enzyme? The only such reactive groups that appear to be identified in the specification or claims as originally filed are a vinylmethylsulfone, chloromethylketone and fluoromethylketone. However, given that the scope of the term "reacting with" is not defined in the specification, it would not be apparent to the artisan would be ascertain that the disclosed groups are representative of the full scope of "groups capable of reacting with active site cysteine of asparaginyl endopeptidase."

In view of the breadth of the claims, the paucity of guidance in the specification and the level of predictability in the art, it would require an undue amount of experimentation on the part of the artisan to practice the invention in a manner commensurate with the scope of the claims and the statute does not sanction this.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is ambiguous and unclear in reciting that the AGNK or KNNE compound is administered with "an effective amount of an agent for the treatment or prevention or amelioration of an autoimmune disease or an allergic or hypersensitivity reaction." If the "agent" is "effective" for treatment or prevention or amelioration, what is the purpose of administering AGNK or KNNE, whose purpose is disclosed as an immune response inhibitor?

Similarly, claim 14 recites that the AGNK or KNNE compound is administered with "an effective amount of an immunosuppressive agent." If the "agent" is "effective" for immunosuppression, what is the purpose of administering AGNK or KNNE, whose purpose is disclosed as an immune response inhibitor?

Conclusion

3. Claims 1-4, 38-41, 57-59 and 68 are allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
April 17, 2006

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644